Remarks

Claims 1-24, 55-81, 183-186, 191, 192 and 203-210 are pending.

Rejections under 35 USC § 103

Curtet and Duclos.

Claims 1-24, 55-81, 183-186, 191, 192 and 203-210 are rejected under 35 USC § 103 as being obvious over Curtet (US Patent No. 4,895,726) in view of Duclos (US Patent 5,776,495).

The claimed invention provides a suspension of an active ingredient, which is an intermediate product which is used in the manufacture of a final composition which exhibits superior results. *See* Specification at page 7, lines 19-21. The suspension, when used in a fluidized bed granulator, provides a final composition having an improved dissolution. The suspension itself is not used as a dosage form for the active ingredient, but as an intermediate in the manufacture of the final dosage form. Again, the claimed invention is dedicated to a product that it not used as a pharmaceutical composition for administration to a patient in need thereof, but to an intermediate product.

The suspension is not used itself as a final composition to be administered to a patient, but as an intermediate product in the process. The process as presently claimed is not a process for obtaining a suspension, but a process which will use the suspension to produce a fenofibrate composition. Consequently, the suspension does not exist in the final product obtained by the claimed process. Only the solid dosage form obtained by the claimed process is administered to a patient.

Applicants respectfully traverse the rejection in the office action because Curtet does not disclose or suggest the claimed suspensions, let alone the processes using them.

Curtet does not disclose or suggest the claimed suspensions. This is again acknowledged by the Examiner in the office action at page 4, third paragraph:

> *"Curtet et al. do not expressly state a fenofibrate suspension, but rather a composition, wherein co-micronized granules are contained in the presence of water."*

The Examiner further states that:

> *"However, it is well known in the art to incorporate a medicament, such as fenofibrate in combination with water and a surfactant to form a suspension."*

As discussed above, the suspensions of the invention are not directly administered to a patient, but are an intermediate product in the manufacture of a final composition. The fact that suspensions are known galenic formulations is irrelevant to the claimed invention which is drawn to a process for making (solid) compositions using a (liquid) suspension.

The Examiner also indicates on page 5 of the office action that:

> *"The expected result would be an improved process for obtaining a bioavailable fenofibrate suspension formulation, which can be administered once a day."*

This, however, is not the claimed invention. The invention is dedicated to a process using a suspension which is sprayed onto inert carriers; the process is not dedicated to obtaining a suspension that can be administered. The suspension is never administered, it is sprayed on carriers, and the resulting composition is either further processed (e.g. compressed into tablets) or used as granules (to be administered to a patient in need thereof).

The PTO contends that it is obvious for the skilled person to modify a solid composition into a liquid, aqueous, suspension (which, again, is not the invention that is claimed). The PTO has indicated in the "Response to Arguments" section that:

> *"The prior art initially recognizes and teaches a similar formulation as claimed, which utilizes the same components as that being claimed by the Applicant."*

Applicant respectfully disagrees. The prior art, i.e. Curtet, only discloses solid dosage forms. *See* abstract and claim 1 of Curtet. It is not disputed that a suspension is a liquid formulation. Thus, it cannot be said that Curtet teaches a "*similar*" formulation as claimed (which again is not correct since the claims are to a process, not a final formulation), because a solid is not "*similar*" to a liquid.

The question is whether the skilled person would have modified Curtet, i.e. would have achieved a process using a liquid suspension containing the active to obtain a final solid dosage form. Duclos and Ikeda do not provide the necessary motivation.

Duclos is relied upon for its teaching an adjunction of non-ionic surfactants, solubilizing agents and micronization. Micronization and surfactants are already present in Curtet, so the only element Duclos would disclose and that would not already be part of Curtet is the use of solubilizing agents. However, this statement is found only in the introductory part of Duclos and is not disclosed elsewhere. Duclos' teaching of solubilizing agents is thus defective. Thus, Duclos cannot fill in the gap between the solid dosage form of Curtet and the liquid suspension of the invention. In any event, Duclos fails to teach a liquid suspension as is – indirectly - acknowledged by the Examiner at paragraph bridging pages 4 & 5.

Ikeda is relied upon for its teaching of suspensions. It is not disputed that suspensions are known galenic formulations. The skilled person would not consider liquid suspensions given the teachings in Curtet. Applicants respectfully submit that Curtet teaches away from a suspension. Indeed, Curtet states (e.g., abstract and claim 1):

> *"a composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant"* (emphasis added).

Thus, Curtet requires the surfactant to be in a solid form. The claimed invention requires the surfactant or the polymer to be in a solution, hence, in a dissolved form, which is very different from a solid form. Accordingly, Curtet cannot render the claimed invention obvious.

Curtet requires that the fenofibrate and the solid surfactant be co-micronized. The skilled person would not manufacture a suspension of fenofibrate in a solution comprising a surfactant. The skilled person would expect to have the fenofibrate in the suspended state and the surfactant in a dissolved state, thus in separate phases. The skilled person would thus expect to lose the benefits described in Curtet i.e. having both components co-present (in the same, solid, phase). The skilled person would not prepare a suspension where the fenofibrate would no longer be together with the surfactant in the same state (solid, co-micronized). Dissolution of surfactant in a solution would cause the surfactant to lose its micronized state. This is opposite what is required in Curtet (column 1, lines 52-53):

> *"The surfactant will be selected from solid surfactants so that is can be co-micronized with the fenofibrate."*

and paragraph bridging columns 4 and 5

> *"[...]a method for improving the bioavailability of fenofibrate in vivo is recommended, the said method comprising co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15μm [...]"*

Curtet requires a solid surfactant and a powder, and thus a solid (dosage form). By changing from a solid into a liquid composition, the principle of operation of Curtet would be changed. However, as is recalled in MPEP at 2143.02, "*the proposed modification cannot change the principle of operation of a reference*".

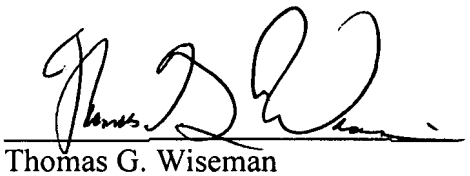
Applicant also wishes to draw the Examiner's attention to the fact that water is used in Curtet to prepare the final granule, and is added to a powder (see above the discussion on the solid aspect) as such, i.e. without any ingredient added thereto. The total amount of water that is used in Curtet is very low, and at no time is the surfactant dissolved in the water added to the powder in Curtet. The invention is drawn to a specific process for making a dosage form which may be a tablet or granulates in a capsule. The process of the invention uses a specific suspension in a spraying process, where the suspension containing the active ingredient is sprayed onto inert carriers. Curtet's process is far different because it uses wet granulation, and never uses a suspension. Water added in the Curtet process only serves granulation and will not allow a solution of surfactant to be obtained. 8.9% of water based on the dry matter is used to granulate, excluding any solution of surfactant dissolved in water. Curtet does not disclose a suspension or a process using a suspension to form a fenofibrate composition.

In view thereof, Applicants respectfully submit that the presently claimed invention is unobvious over Curtet in view of Ikeda, and respectfully request that the rejection under 35 USC § 103 be withdrawn.

Conclusion

An early and favorable reconsideration and allowance of claims 1-24, 55-81, 183-186, 191, 192 and 203-210 is respectfully requested. Examiner Sheikh is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,



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